

|   |                        |              |            |  |
|---|------------------------|--------------|------------|--|
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br>( Not for submission under 37 CFR 1.99) | Application Number     |              | 10595971   |  |
|   | Filing Date            |              | 2006-05-23 |  |
|   | First Named Inventor   | Humphrey     |            |  |
|   | Art Unit               | NA           |            |  |
|   | Examiner Name          | Not Assigned |            |  |
|   | Attorney Docket Number | 80-06        |            |  |

| U.S. PATENTS  |         |               |                        |            |   | <a href="#">Remove</a>   |
|---|---------|---------------|------------------------|------------|---|--|
| Examiner Initial*   | Cite No | Patent Number | Kind Code <sup>1</sup> | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear |
|   | 1       | 5714576       |                        | 1998-02-03 | Hruby et al.                                    |  |
|   | 2       | 5683981       |                        | 1997-11-04 | Hruby et al.                                    |  |
|   | 3       | 5674839       |                        | 1997-10-07 | Hruby et al.                                    |  |
|   | 4       | 5049547       |                        | 1991-09-07 | Hruby et al.                                    |  |
|   | 5       | 4918055       |                        | 1990-04-17 | Hruby et al.                                    |  |
|   | 6       | 4866038       |                        | 1989-09-12 | Hruby et al.                                    |  |
|   | 7       | 4485039       |                        | 1989-11-27 | Hruby et al.                                    |  |
|   | 8       | 4457864       |                        | 1984-07-03 | Hruby et al.                                    |  |
| If you wish to add additional U.S. Patent citation information please click the Add button. |         |               |                        |            |   | <a href="#">Add</a>  |

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

|                        |              |
|------------------------|--------------|
| Application Number     | 10595971     |
| Filing Date            | 2006-05-23   |
| First Named Inventor   | Humphrey     |
| Art Unit               | NA           |
| Examiner Name          | Not Assigned |
| Attorney Docket Number | 80-06        |

**U.S. PATENT APPLICATION PUBLICATIONS**

[Remove](#)

| Examiner Initial* | Cite No | Publication Number | Kind Code <sup>1</sup> | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear |
|-------------------|---------|--------------------|------------------------|------------------|---|--|
|                   | 1       |                    |                        |                  |   |  |

If you wish to add additional U.S. Published Application citation information please click the Add button [Add](#)

**FOREIGN PATENT DOCUMENTS**

[Remove](#)

| Examiner Initial* | Cite No | Foreign Document Number <sup>3</sup> | Country Code <sup>2</sup> j | Kind Code <sup>4</sup> | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear | T <sup>5</sup>           |
|-------------------|---------|--------------------------------------|-----------------------------|------------------------|------------------|---|--|--------------------------|
|                   | 1       | 05048967                             | WO                          |                        | 2005-06-02       | Humphrey  |  | <input type="checkbox"/> |
|                   | 2       | 03072072                             | WO                          |                        | 2003-09-04       | Dorr et al.                                     |  | <input type="checkbox"/> |
|                   | 3       | 87004623                             | WO                          |                        | 1987-08-13       | Hruby et al.                                    |  | <input type="checkbox"/> |
|                   | 4       | 618733                               | AU                          |                        | 1992-01-09       | Hruby et al.                                    |  | <input type="checkbox"/> |
|                   | 5       | 597630                               | AU                          |                        | 1990-06-07       | Hruby et al.                                    |  | <input type="checkbox"/> |

If you wish to add additional Foreign Patent Document citation information please click the Add button [Add](#)

**NON-PATENT LITERATURE DOCUMENTS**

[Remove](#)

| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>5</sup> |
|--------------------|---------|---|----------------|
|--------------------|---------|---|----------------|

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

|                        |              |
|------------------------|--------------|
| Application Number     | 10595971     |
| Filing Date            | 2006-05-23   |
| First Named Inventor   | Humphrey     |
| Art Unit               | NA           |
| Examiner Name          | Not Assigned |
| Attorney Docket Number | 80-06        |

|    |   |                          |
|----|---|--------------------------|
| 1  | Abdel-Malek et al. (Feb. 1995) "Mitogenic and Melanogenic Stimulation of Normal Human Melanocytes by Melanotropic Peptides," Proc. Natl. Acad. Sci. USA 92(5):1789-1793   | <input type="checkbox"/> |
| 2  | Abdel-Malek et al. (Oct. 1999) "The Melanocortin-1 Receptor and Human Pigmentation," Ann. N.Y. Acad. Sci. 885:117-133   | <input type="checkbox"/> |
| 3  | Abel-Malek et al. (2000) "The Melanocortin-1 Receptor is a Key Regulator of Human Cutaneous Pigmentation," Pigment Cell Res. 13(Sup. 8):156-162   | <input type="checkbox"/> |
| 4  | Bastiaens et al. (2001) "Melanocortin-1 Receptor Gene Variants Determine the Risk of Nonmelanoma Skin Cancer Independently of Fair Skin and Red Hair," Am. J. Hum. Genet. 68(4):884-894                                     | <input type="checkbox"/> |
| 5  | Box et al. (1997) "Characterization of Melanocyte Stimulating Hormone Receptor Variant Alleles in Twins with Red Hair," Hum. Mol. Genet. 6(11):1891-1897  | <input type="checkbox"/> |
| 6  | De Luca et al. (1993) "Alpha Melanocyte Stimulating Hormone (Alpha MSH) Stimulates Normal Human Melanocyte Growth by Binding to High-Affinity Receptors," J. Cell. Sci. 105(4):1079-1084                                    | <input type="checkbox"/> |
| 7  | Dorr et al. (2000) "Increased Eumelanin Expression and Tanning is Induced by a Superpotent Melanotropin [Nle4-D-Phe7]-Alpha-MSH in Humans," Photochem. Photobiol. 72(4):526-532   | <input type="checkbox"/> |
| 8  | Dwyer et al. (1998) "The Use of Spectrophotometry to Estimate Melanin Density in Caucasians," Cancer Epidemiol. Biomarkers Prev. 7(3):203-206   | <input type="checkbox"/> |
| 9  | Dwyer et al. (2002) "Cutaneous Melanin Density of Caucasians Measured by Spectrophotometry and Risk of Malignant Melanoma Basal Cell Carcinoma, and Squamous Cell Carcinoma of the Skin," Am. J. Epidemiol. 155 (7):614-621 | <input type="checkbox"/> |
| 10 | Fitzpatrick, T.B. (1988) "The Validity and Practicality of Sun-Reactive Skin Types I Through VI," Arch. Dermatol. 124 (6):869-871   | <input type="checkbox"/> |
| 11 | Frandsen et al. (1998) "Human Pigmentation Phenotype: A Point Mutation Generates Nonfunctional MSH Receptor," Biochem. Biophys. Res. Commun. 245(2):490-492   | <input type="checkbox"/> |

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

|                        |              |
|------------------------|--------------|
| Application Number     | 10595971     |
| Filing Date            | 2006-05-23   |
| First Named Inventor   | Humphrey     |
| Art Unit               | NA           |
| Examiner Name          | Not Assigned |
| Attorney Docket Number | 80-06        |

|    |   |                          |
|----|---|--------------------------|
| 12 | Healy et al. (2001) "Functional Variation of MC1R Alleles from Red-Haired Individuals," Hum. Mol. Genet. 10 (21):2397-2402  | <input type="checkbox"/> |
| 13 | Hunt et al. (1994) "Alpha-Melanocyte Stimulating Hormone and Its Analogue Nle4DPhe7 Alpha-MSH Affect Morphology, Tyrosinase Activity and Melanogenesis in Cultured Human Melanocytes," J. Cell. Sci. 107(1):205-211             | <input type="checkbox"/> |
| 14 | Hunt et al. (1995) "Nle4DPhe7 Alpha-Melanocyte-Stimulating Hormone Increases the Eumelanin:Phaeomelanin Ratio in Cultured Human Melanocytes," J. Invest. Dermatol. 104(1):83-85   | <input type="checkbox"/> |
| 15 | Jimenez-Cervantes et al. (2001) "Thr40 and Met122 are New Partial Loss-of-Function Natural Mutations of the Human Melanocortin 1 Receptor," FEBS Lett. 508(1):44-48   | <input type="checkbox"/> |
| 16 | John et al. (2002) "Four Novel Variants in MC1R in Red-Haired South African Individuals of European Descent: S83P, Y152X, A171D, P256S," Hum. Mutat. 19(4):461-462  | <input type="checkbox"/> |
| 17 | Kadekaro et al. (Jun. 2003) "Significance of the Melanocortin 1 Receptor in Regulating Human Melanocyte Pigmentation, Proliferation, and Survival," Ann. N.Y. Acad. Sci. 994:359-365  | <input type="checkbox"/> |
| 18 | Kennedy et al. (2001) "Melanocortin 1 Receptor (MC1R) Gene Variants are Associated with and Increased Risk for Cutaneous Melanoma Which is Largely Independent of Skin Type and Hair Color," J. Invest Dermatol. 117(2):294-300 | <input type="checkbox"/> |
| 19 | Levine et al. (1991) "Induction of Skin Tanning by Subcutaneous Administration of a Potent Synthetic Melanotropin," JAMA 266(19):2730-2736  | <input type="checkbox"/> |
| 20 | Menon et al. (1983) "A Comparative Study of the Physical and Chemical Properties of Melanins Isolated from Human Black and Red Hair," J. Invest. Dermatol. 80(3):202-206  | <input type="checkbox"/> |
| 21 | Menon et al. (1983) "Effects of Ultraviolet-Visible Irradiation in the Presence of Melanin Isolated from Human Black or Red Hair Upon Ehrlich Ascites Carcinoma Cells," Cancer Res. 43(7):3165-3169                             | <input type="checkbox"/> |
| 22 | Palmer et al. (2000) "Melanocortin-1 Receptor Polymorphisms and Risk of Melanoma: Is the Association Explained Solely by Pigmentation Phenotype," Am. J. Hum. Genet. 66(1):176-186  | <input type="checkbox"/> |

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

|                        |              |            |
|------------------------|--------------|------------|
| Application Number     |              | 10595971   |
| Filing Date            |              | 2006-05-23 |
| First Named Inventor   | Humphrey     |            |
| Art Unit               | NA           |            |
| Examiner Name          | Not Assigned |            |
| Attorney Docket Number | 80-06        |            |

|    |  |                          |
|----|--|--------------------------|
| 23 | Sanchez et al. (2002) "Loss-of-Function Variants of the Human Melanocortin-1 Receptor Gene in Melanoma Cells Define Structural Determinants of Receptor Function," Eur. J. Biochem. 269(24):6133-6141                | <input type="checkbox"/> |
| 24 | Sawyer et al. (Oct. 1980) "4-Norleucine, 7-D-Phenylalanine-Alpha-Melanocyte-Stimulating Hormone: A Highly Potent Alpha-Melanotropin with Ultralong Biological Activity," Proc. Natl. Acad. Sci. USA 77(10):5754-5758 | <input type="checkbox"/> |
| 25 | Schiöth et al. (1999) "Loss of Function Mutations of the Human Melanocortin 1 Receptor are Common and are Associated with Red Hair," Biochem. Biophys. Res. Commun. 260(2):488-491                                   | <input type="checkbox"/> |
| 26 | Scott et al. (2002) "Human Melanocortin 1 Receptor Variants, Receptor Function and Melanocyte Response to UV Radiation," J. Cell. Sci. 115(11):2349-2355   | <input type="checkbox"/> |
| 27 | Smith et al. (1998) "Melanocortin 1 Receptor Variants in an Irish Population," J. Invest. Dermatol. 111(1):119-122   | <input type="checkbox"/> |
| 28 | Sturm et al. (Oct. 2002) "Skin Colour and Skin Cancer – MC1R, The Genetic Link," Melanoma Res. 12(5):406-416   | <input type="checkbox"/> |
| 29 | Sturm et al. (2003) "Genetic Association and Cellular Function of MC1R Variant Alleles in Human Pigmentation," Ann. N.Y. Acad. Sci. 994:348-358  | <input type="checkbox"/> |
| 30 | Valverde et al. (1996) "The Asp84Glu Variant of the Melanocortin 1 Receptor (MC1R) is Associated with Melanoma," Hum. Mol. Genet. 5(10):1663-1666  | <input type="checkbox"/> |

If you wish to add additional non-patent literature document citation information please click the Add button

**EXAMINER SIGNATURE**

|                    |                   |                 |            |
|--------------------|-------------------|-----------------|------------|
| Examiner Signature | /Ronald Niebauer/ | Date Considered | 05/14/2009 |
|--------------------|-------------------|-----------------|------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.